REMARKS

I. Status of the Claims

Claims 1-22 are pending. Claims 1, 2, 7, and 9-19 are under examination. Claims 3-6, 8, 20 and 21 are withdrawn.

II. The Claims Are Drawn to Statutory Subject Matter

The Examiner rejects claims 1, 2, 7, and 9-19 under 35 U.S.C. § 101, because "polynucleotide" in the claims allegedly "reads upon a naturally occurring polynucleotide, which is a product of nature that does not clearly show the 'hand of man.'" Office Action, p. 7.

Solely to advance prosecution and without disclaimer of or prejudice to the subject matter recited therein, Applicants have amended independent claim 1 by inserting "an isolated" before "polynucleotide." The dependent claims were not amended as they depend from the amended claim and recite the polynucleotide of claim 1.

Applicants respectfully assert that the amended claims do not read on a product of nature and request that the Examiner withdraw the rejection.

III. The Dependent Claims Recite Elements with Antecedent Basis

The Examiner rejects claims 11 and 13 under 35 U.S.C. § 112, second paragraph, for the alleged lack of antecedent basis. Office Action, pp. 7-8. The Examiner asserts that claim 9, from which claims 11 and 13 depend, recites a protein or RNA of therapeutic interest, while claims 11 and 13 recite a protein of therepeutic interest. *Id.*

Without acquiescing in the rejection and without disclaimer of or prejudice to the subject matter recited therein, Applicants have deleted "of therapeutic interest" in claims 11 and 13. Amended claims 11 and 13 now recite "the protein" which has antecedent basis in claim 9. The Examiner is referred to the Examiner's amendment in the Notice of Allowability mailed November 16, 2006 in the parent case (U.S. Application Serial No. 10/005,337), in which a similar amendment was made by the Examiner to overcome a similar rejection. Notice of Allowability, November 16, 2006, p. 2. Also see, Office Action, September 18, 2006, p. 3.

Applicants respectfully request the Examiner withdraw the rejection.

IV. The Claims Satisfy the Written Description Requirement

The Examiner rejects claims 1, 2, 7, and 9-19 under 35 U.S.C. § 112, first paragraph, for allegedly failing to meet the written description requirement. Specifically, the Examiner asserts that "the specification fails to adequately describe those polynucleotides comprising a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO: 3 which retain the function of specifically inducing expression in cardiac cells in vivo of a gene which is operably linked to said polynucleotide as instantly claimed." Office Action, p. 9.

The disclosure of the specification demonstrates that Applicants had possession of the claimed polynucleotides when the application was filed. The written description requirement is met if the specification discloses "functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (*quoting* Guidelines for Examination of Patent Applications

Under the 35 U.S.C. 112, P 1 "Written Description" Requirement, 66 Fed. Reg. at 1106 ("Guidelines")).

As in *Enzo*, the correlation between structure and function is based on hybridization between nucleic acids[1] and the instant claims closely parallel Example 9 of the Guidelines. Guidelines, p. 35. The specification discloses a novel and non-obvious sequence. That sequence falls within the claimed genus and there is actual reduction to practice of the claimed sequence. Finally, one of skill in the art would not expect great variation within the genus because the "art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing." *Id.* at 36. Accordingly, the conclusion in the instant case is the same as in Example 9 of the Guidelines: "Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention." *Id.*

Applicants respectfully assert that claims 1, 2, 7, and 9-19 meet the written description requirement and request that the Examiner withdraw the rejection.

V. The Claims are not Anticipated

The Examiner rejects claims 1, 2, 7, and 9-19 under 35 U.S.C. 102(b) as allegedly anticipated by WO0246220 ("Schwartz"), Kuo *et al.*, "Control of Segmental Expression of the Cardiac-Restricted Ankyrin Repeat Protein Gene by Distinct Regulatory Pathway in Murine Cardiogenesis," Development, 126: 4223-34 (1999) ("Kuo") and GenBank Accession No. AF131994 ("Aihara"). Each publication is

1 *Enzo*, 323 F.3d at 967.

discussed separately. As set forth below, none of the publications relied on by the Examiner disclose the same subject matter recited in the claims and thus they cannot anticipate the claimed invention.

A. Schwartz

The Examiner rejects claims 1, 2, 7, and 9-19 as allegedly anticipated by Schwartz. Office Action, p. 12. According to the Examiner, Schwartz discloses and claims a polynuclotide sequence of the mouse CARP gene that specifically induces expression in cardiac cells in vivo of a gene that is linked to the CARP sequence. *Id.* The Examiner compares the sequence disclosed in Schwartz with SEQ ID NO: 3 using the BLAST algorithm, and asserts that the Schwartz sequence "has 80% overall identity with SEQ ID NO: 3 of the instant invention and represents a 'fragment' of SEQ ID NO: 3." *Id.* The Examiner considers a sequence greater that 20 bp of SEQ ID NO: 3 to be a "fragment." *Id.* The Examiner further asserts that the sequence of Schwartz is "replete with fragments of SEQ ID NO: 3." *Id.* at 13. Apparently, the Examiner considers the regions of 100% identity between the two sequences to be "fragments." Finally, the Examiner states that Schwartz discloses expression cassettes, vectors and therapeutic proteins and RNAs in combination with the sequence disclosed in Schwartz. *Id.*

Schwartz is not prior art to the instant application, as it is an application in the chain of priority of the instant application. The instant application is a continuation-in-part of U.S. Application 10/005,337, which claims priority to U.S. Provisional Application Serial No. 60/251,582 ("the '582 application"). Schwartz is the PCT publication of the '582 application. Thus, the instant application is entitled to the filing date of Schwartz

for all Schwartz discloses. Thus, Schwartz did not publish before the filing date of the instant application and cannot constitute prior art under 35 U.S.C. 102(b).

Moreover, the Examiner's position regarding the disclosure of Schwartz is internally contradictory. According to the Examiner, the parent of the instant application does not provide support for fragments. Office Action, p. 6. The Examiner asserts that the application is afforded priority to March 17, 2004, the filing date of the instant application because the disclosure of the parent "do[es] not have support for a polynucleotide comprising a fragment of SEQ ID NO: 3." *Id.* The Examiner nevertheless concludes that SEQ ID NO: 1 of Schwartz, which comprises the mouse CARP gene and is identical to SEQ ID NO:1 of the instant application, "is replete with fragments of SEQ ID NO: 3." It is not possible for Schwartz to fail to provide support for fragments while at the same time anticipating the instantly claimed fragments.

Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

Even if Schwartz were a publication within the meaning of 35 U.S.C. § 102(b), which it is not, SEQ ID NO: 1 of Schwartz cannot anticipate claims 1, 7 or 9-19 as this sequence is not identical to a polynucelotide comprising either SEQ ID NO: 3 or the claimed fragments of SEQ ID NO: 3. Applicants amended the claims to recite SEQ ID NO: 3 and specific fragments of that sequence. SEQ ID NO: 1 of Schwartz, which is derived from the **mouse** CARP1 gene, not the **human** CARP1 gene, does not anticipate SEQ ID NO: 3, or the claimed fragments thereof, because SEQ ID NO: 1 of Schwartz is neither the claimed sequence nor the claimed fragments.

SEQ ID NO: 1 of Schwartz thus fails to disclose all the elements of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co.* 814 F.2d 628, 631 (Fed. Cir. 1987). As indicated by the sequence alignment prepared by the Examiner, 2033 bp from the 5' end of SEQ ID NO: 3 show no significant alignment with the SEQ ID NO: 1 of Schwartz. Similarly, 19 nucleotides from the 3' end of SEQ ID NO: 3 show no significant alignment with the SEQ ID NO: 1 of Schwartz. Thus, Schwartz does not anticipate SEQ ID NO: 3 because it only discloses part of a sequence that is similar, but not identical, to SEQ ID NO: 3.

SEQ ID NO: 1 of Schwartz also fails to anticipate the claimed fragments of SEQ ID NO: 3. As noted above, the Schwartz sequence does not align with SEQ ID NO: 3 upstream of bp 2034. The 5' ends of the claimed fragments all begin before bp 2034. Thus, these polynucleotides contain sequences at their 5' ends not disclosed by SEQ ID NO: 1 of Schwartz. As noted above, 19 nucleotides from the 3' end SEQ ID NO: 3 show no significant alignment with the SEQ ID NO: 1 of Schwartz. The claimed fragments all have the same 3' end, and SEQ ID NO: 1 of Schwartz is lacking 19 bp from that end.

Thus, Schwartz does not anticipate claims 1, 7, or 9-19 and Applicants respectfully request the Examiner withdraw the rejection.

B. Kuo

The Examiner rejects claims 1, 2, 7, 15, 17, and 19 as allegedly anticipated by Kuo. Office Action, p. 14. According to the Examiner, Kuo discloses the cloning of the mouse CARP gene and the sequence 2.5 kb upstream of the murine CARP coding

sequence. *Id.* The Examiner states that a 337 bp sequence disclosed in Kuo, p0.295Luc, is 82% identical to SEQ ID NO: 3, and thus "represents a 'fragment' of SEQ ID NO: 3." *Id.* The Examiner further asserts that Kuo discloses transfection using calcium phosphate, a "pharmaceutically acceptable carrier." *Id.*

Kuo does not anticipate SEQ ID NO: 3, or the claimed fragments thereof, because Kuo does not disclose the claimed sequences, and thus fails to disclose all the elements of the claim. The claims have been amended to recite SEQ ID NO: 3 and specific fragments of that sequence. Kuo discloses part of the **mouse** CARP gene, not the **human** CARP gene, and these sequences are not identical in length to each other. The alignment of the Kuo sequence with SEQ ID NO: 3 only begins at bp 2402 of SEQ ID NO: 3 and ends at bp 2721. Thus, SEQ ID NO: 3, and the claimed fragments of SEQ ID NO: 3, contain nucleotides at their 5' and 3' ends that are not disclosed by Kuo. Because Kuo only discloses a sequence that is similar to part of the claimed sequences but does not disclose sequences present in the 5' and 3' ends of SEQ ID NO: 3 and the claimed fragments thereof, Kuo does not anticipate the claimed sequences.

Applicants respectfully request the Examiner withdraw the rejection of claims 1, 7, 15, 17, and 19 over Kuo.

C. Aihara

The Examiner rejects claims 1 and 2 as allegedly anticipated by Aihara. According to the Examiner, Aihara discloses a 2047 bp sequence from the human CARP 1 promoter that is 98% identical to SEQ ID NO: 3 that is "replete with fragments of SEQ ID NO: 3." Office Action, p. 16.

Aihara also fails to anticipate the claimed nucleotides, and fragments thereof, as Aihara discloses a sequence that differs in length and sequence from the claimed sequences. SEQ ID NO: 2 is the same as the Aihara sequence. Applicants have amended the claims to recite SEQ ID NO: 3 and specific fragments of that sequence, with the proviso that the claimed polynucleotide does not comprise from nucleotide 2053 to nucleotide 2074 of SEQ ID NO: 2. Thus Aihara does not anticipate SEQ ID NO: 3, or the claimed fragments thereof, because the Aihara sequence is neither the claimed sequence nor the claimed fragments of that sequence. The claimed polynucleotides do not comprise nucleotide 2053 to nucleotide 2074 of SEQ ID NO: 2, and thus do not comprise the Aihara sequence. Moreover, as indicated by the alignment provided by the Examiner, the 5' end of SEQ ID NO: 3 contains sequence that does not align with that of Aihara. In other words, Aihara fails to disclose sequence that is present at the 5' end in SEQ ID NO: 3. Aihara also fails to disclose sequence that is present at the 5' end of a fragment of SEQ ID NO: 3 comprising nucleotide 594 to nucleotide 2740 (SEQ ID NO: 4). Thus, Aihara fails to disclose the claimed sequences, and Applicants respectfully request the withdrawal of the rejection of claims 1 and 2.

CONCLUSION

In view of these amendments and remarks, Applicants submit that the application is in condition for allowance.

Please grant any extensions of time required to enter this paper and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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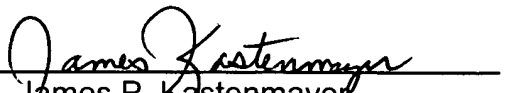
By: 

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